DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2014

Merit Medical Systems Inc.
Mr. Michael O'Sullivan
RA Specialist III
Parkmore Business Park West
Galway, Ireland

Re: K142051
Trade/Device Name: Prelude Plastic Jacketed Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 14, 2014
Received: November 17, 2014

Dear Mr. Michael O'Sullivan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142051

Device Name
Prelude Plastic Jacketed guide wire

Indications for Use *(Describe)*
The Merit plastic jacketed introducer guide wire is intended to facilitate the placement of devices during diagnostic and interventional procedures, specifically sheath introducers. The wire is indicated for the peripheral vasculature only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K142051
510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Registration Number: Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (+353) 91 703700 (Ext. 3061) (+353) 91 680104 Mark Mullaney 1721504 Merit Medical Ireland Ltd. Parkmore Business Park Parkmore, Galway, Ireland (+353) 91 703700 (Ext. 3223) (+353) 91 680104 Michael O'Sullivan 17th December 2014 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Prelude Plastic jacketed introducer guide wire Guide Wire Wire, Guide, Catheter
Predicate Device	**Premarket Notification Predicate Device # 1:** Terumo Glidesheath(mini guide wire): K082644 Manufacturer: Terumo Medical Corporation	
Classification	Class II 21 CFR § 870.1330 Product code: DQX Division of Cardiovascular Devices	
Intended Use	The Merit Prelude Plastic Jacketed introducer guide wire is intended to facilitate the placement of devices during diagnostic and interventional procedures, specifically sheath introducers. The wire is indicated for the peripheral vasculature only.	
Device Description	The Merit Prelude Plastic jacketed introducer guide wire consists of a high quality metallic core wire with a radiopaque polymer jacket. The wire will be offered in straight and angled versions, in various lengths.	

Comparison to Predicate	The Technological characteristics of the subject Merit Prelude Plastic jacketed introducer guide wire are substantially equivalent to those of the mini guide wire predicate, within the Terumo Glidesheath (mini guide wire) Wire [K082644]. Both wires consist of a metallic core wire coated in a radiopaque polymer jacket.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. Where appropriate, the tests were based on the requirements of the following documents: • FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995. • ISO 11070: 1998, *Sterile Single-Use Intravascular Catheter Introducers.* • ISO 11135-1: 2007 *Sterilization of health care products-Ethylene oxide-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.* • ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* • ISO 2233:2000, Packaging – Complete, filled transport packages and unit loads – Conditioning for testing • ISO 10993-1: 2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1. • ANSI/AAMI/ISO 10993-3:2003, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity* • ISO 10993-4:2002 (Amd.1:2006)*, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood* • ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* • ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* • ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* • ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* • ASTM F756-08, *Standard practice for assessment of hemolytic properties of materials* • United States Pharmacopeia 36, National Formulary 31, <151> Pyrogen Test. 2013 The following is a list of all significant testing that was successfully completed: <u>Performance Testing-Bench</u> • Size Designation

- Radiodetectability
- Surface
- Tensile Strength
- Torque Strength
- Tip Flexibility
- Fracture test
- Flex test
- IV Catheter Compatibility
- Dilator Catheter Compatibility
- Corrosion Resistance
- Tip Shape Testing
- ETO Residuals
- Bioburden
- Pyrogen (LAL)

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation
- Chemical Characterization

As all test results were comparable to the predicate device and as the subject Merit Prelude Plastic jacketed introducer guide wire met the predeterminded acceptance criteria applicable to the safety and efficacy of the device, this has demonstrated that the subject device is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

Based on the Indications for Use, design, safety and performance testing, the subject Merit Prelude Plastic jacketed introducer guide wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the predicate device, the Terumo Glidesheath(mini guide wire) manufactured by Terumo Medical Corporation, K082644.